

### **REMARKS**

The present Office Action addresses and rejects claims 1-13. Applicants respectfully request reconsideration of the present application in view of the following remarks.

#### ***Rejections Pursuant to 35 U.S.C. §102***

Claims 1-3, 5-7, and 9-12 stand rejected pursuant to 35 U.S.C. 102(e) as being unpatentable over U.S. Patent No. 6,685,706 to Padget et al. ("Padget"). Applicants respectfully disagree.

Independent claims 1, 5, and 9 each recite a bioabsorbable medical device having a *bioabsorbable lubricating coating* disposed on at least a portion thereof. Claims 1, 5, and 9 also recite that the coating reduces *device drag* between the contact surfaces of the device. Padget fails to teach or suggest either a bioabsorbable lubricating coating or a coating that reduces device drag between the contact surfaces of a device.

The Examiner asserts that Padget discloses "a bioabsorbable lubricating coating, as set forth in column 4, lines 32-41, disposed on at least a section of each of the first and second contact surfaces." This is incorrect. Padget actually discloses "a bioabsorbable polymeric coating layer on part or all of the anchor surface," not a bioabsorbable lubricating coating or a coating on contact surfaces. Padget at col. 24, lines 32-34.

First, Padget fails to teach or suggest a coating that is a *lubricating* coating. To the contrary, Padget discloses that the "polymeric coating" may contain "bioactive substances" that "contribute to the healing of the injury in addition to providing mechanical support." Padget at col. 24, lines 33-41. Thus, Padget discloses a coating that contributes to healing rather than a lubricating coating that provides reduced device drag between contact surfaces. The Examiner also incorrectly asserts that Padget discloses that "the bioabsorbable coating comprises polylactic acid." Padget provides no such disclosure. Padget merely discloses a variety of polymers that can be used to form the body of the device, not for use as a coating. *See* Padget at col. 22, line 33 to col. 23, line 22. There is simply no teaching or suggestion in Padget regarding the use of the listed polymers as a lubricating coating.

Second, there is no teaching or suggestion that the coating is disposed on *contact surfaces* of the device. Instead, the coating is disclosed as being on the “anchor surface.” The only anchor surfaces disclosed by Padget are the proximal anchor 36 and/or the distal anchor 34. The surfaces of the distal anchor 34 and proximal anchor 36 do not engage each other. Indeed, they do not even contact each other. *See* Padget at FIG. 1. Thus, not only is Padget’s “bioabsorbable polymeric coating” not a lubricating coating, it is also not disposed on contact surfaces of the device. There is therefore simply no teaching or suggestion in Padget to use any lubricating coating to reduce device drag between contact surfaces of a device.

Accordingly, independent claims 1, 5, and 9, as well as claims 2-4, 6-8, and 11-13 which depend directly or indirectly therefrom distinguish over Padget and represent allowable subject matter.

### ***Rejections Pursuant to 35 U.S.C. §103***

Claims 4, 8, and 13 stand rejected pursuant to 35 U.S.C. 103(a) as being unpatentable over Padget in view of U.S. Patent No. 5,458,653 to Davidson (“Davidson”). Applicants respectfully disagree.

At the outset, claims 4, 8 and 13 depend from claims 1, 5, and 9, respectively, and therefore distinguish over Padget for at least the reasons discussed above. Davidson fails to remedy the deficiencies of Padget regarding a bioabsorbable lubricating coating that reduces device drag between contact surfaces of a device. Like Padget, Davidson fails to teach or suggest a lubricating coating. Davidson instead discloses coatings on the bone-contacting surfaces of joint prostheses to “counteract stress shielding” and to “initially retard anchoring of the prosthesis in the bone.” Davidson at col. 3, lines 3-40, col. 5, lines 4-5. Thus Davidson also fails to teach or suggest any lubricating coating or any coating to reduce device drag between contact surfaces of a device. Davidson therefore fails to remedy the deficiencies of Padget with respect to claims 1, 5, and 9.

The Examiner also admits that Padget fails to disclose “a coating comprising 90/10 polycaprolactone/polyglycolide copolymer.” The Examiner thus relies on Davidson to provide “the evidences [sic] the use of a coating comprising polycaprolactone/polyglycolide copolymer

to avoid bone resorption caused by stress shielding.” However, Davidson merely discloses “appropriate copolymers” of number of listed polymers, but Davidson is directed only to coatings to counteract stress shielding. *See* Davidson at col. 3. lines 40-49. Thus, the disclosure by Davidson of “appropriate copolymers” is related only to use of those copolymers to counteract stress shielding, not for lubrication. Davidson also fails to disclose the claimed copolymer ratio claimed by Applicants. Nevertheless, the Examiner proceeds to argue that the claimed ratio would have been obvious on the basis that “where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.” Such an argument is improper here because neither reference discloses the general conditions of the claim, i.e., lubricating coatings. Thus, the specific lubricating coating claimed by Applicants would not have been obvious without the impermissible application of hindsight by the Examiner to the teachings of Padget and Davidson.

Moreover, the Examiner not only disregards the deficiencies in the references, but also fails to provide a valid reason to modify Padget in view of Davidson. The Examiner states that the motivation or rationale for the combination would be “to avoid bone resorption caused by stress shielding.” However, if Padget were modified in view of Davidson to include a coating to avoid bone resorption caused by stress shielding, then the combination would still fail to remedy the deficiencies of both references. As noted above, neither reference teaches or suggests a lubricating coating on contact surfaces of a device for reducing device drag between those contact surfaces because neither reference discloses a lubricating coating, a lubricating coating on contact surfaces, or that such a coating could be used to reduce device drag. Even if one of skill in the art would have modified Padget in view of Davidson to avoid bone resorption caused by stress shielding, as argued by the Examiner, the coatings of Davidson would presumably be added to the surfaces of Padget that are in contact with the bone, not to contact surfaces of the device to reduce device drag between those surfaces. Such a modification would fail to teach or suggest the claimed invention. Indeed, without benefit of Applicants’ disclosure, one of ordinary skill in the art relying on the disclosures of Padget and Davidson would not even consider the problem of device drag.

Accordingly, independent claims 1, 5, and 9, as well as claims 2-4, 6-8, and 11-13 which

depend directly or indirectly therefrom distinguish over Padget and Davidson, alone or in combination, and represent allowable subject matter.

***Conclusion***

In view of the foregoing, Applicants submit that all previously submitted claims, as amended, are now in condition for allowance, and allowance thereof is respectfully requested. Examiner Philogene is urged to telephone the undersigned attorney for Applicants if such communication is deemed to expedite prosecution of this application.

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Respectfully submitted,

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